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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/668,181  | 09/24/2003  | Caroline Osterhoff   | 35-268              | 5220             |
| 7590  | 11/29/2005  |                      | EXAMINER            |                  |
| Millen, White, Zelano & Branigan, P.C.<br>2200 Clarendon Boulevard<br>Suite 1400<br>Arlington, VA 22201 |             |                      | ULM, JOHN D         |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1649                |                  |

DATE MAILED: 11/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/668,181             | OSTERHOFF ET AL.    |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | John D. Ulm            | 1649                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 05 October 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 6-16, 18-20 and 23-30 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-5, 17, 21 and 22 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/24/03</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____ .                                  |

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1) Claims 1 to 30 are pending in the instant application.

2) Claims 6 to 16, 18 to 20 and 23 to 30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the correspondence filed 05 October of 2005. The traversal is on the ground(s) that a search of the different inventions in a single application would pose no undue burden. This is not found persuasive because M.P.E.P. 803 states that:

“For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02. That prima facie showing may be rebutted by appropriate showings or evidence by the applicant.”

Serious burden was shown in the original requirement by the separate classification and separate status in the art of the different inventions. Applicant has provided neither a showing or evidence to the contrary. Applicant's request for rejoinder of process claims with the elected product claims is inappropriate at this time since no product claim has been allowed.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3) Claims 1 to 5, 17, 21 and 22 are rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility. The instant claims are drawn to an isolated mammalian epididymis-

specific receptor that lacks a specific and substantial utility in currently available form because the instant application does not disclose an established specific biological role for this protein or its significance to a particular disease, disorder or physiological process which one would wish to manipulate for a desired clinical effect.

It is clear from the instant specification that the receptor protein described therein as an epididymis-specific receptor is what is termed an "orphan receptor" in the art. This is a protein whose putative function as a receptor is based upon its structural similarity to known receptor proteins. There is little doubt that, after complete characterization, this protein may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken Applicant's claimed invention is incomplete. Whereas one could readily employ a putative receptor protein of the instant invention in an assay to identify ligands thereto the information obtained thereby would be of little use until one discovers the identity of those physiological processes moderated by the interaction of that ligand with that putative receptor. Because the instant specification has failed to credibly identify a physiological process which has been shown to be influenced by the activation or inhibition of a putative receptor protein of the instant invention an artisan would have no way of predicting what effects the administration of that ligand to an organism would have. If one can not predict the effects that the administration of a ligand of the putative receptor of the instant invention is going to have on an organism then it is unclear as to what practical benefit is derived by the public from the identification of that ligand.

The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", " [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

The instant claims are drawn to a protein of as yet undetermined function or biological significance. The fact that this protein is only expressed in epididymis does not provide a substantial utility since the instant specification does not identify any disease or disorder which can be diagnosed by the detection of the presence or absence of this protein or which can be treated by the addition or removal of this protein.

The employment of a protein of the instant invention as a tissue specific marker is not a substantial or specific utility since epididymis specific proteins were already known in the art. Further, all human proteins can invariably be classified into two

categories, those that are expressed in a tissue or developmentally specific manner and those which are expressed ubiquitously. It can be alleged that any protein which is expressed in a tissue specific manner can be employed to detect the tissue in which it is expressed in a sample. Alternately, a human protein which is expressed ubiquitously can be employed to detect the presence of any human tissue in a sample. Such utilities are analogous to the assertion that a particular protein can be employed as a molecular weight marker, which is neither a specific or substantial utility.

The employment of the instant protein as an antigen in a male contraceptive formulation as asserted in the instant specification would be substantial and specific, however such a process is not enabled by the instant specification. As conceded in the concluding paragraph of Applicant's own peer reviewed publication Osterhoff et al. (DNA and Cell Biol. 16(4):379-389, Apr. 1997), "[f]urther research is essential" "to examine the suitability of HE6 as a target for the development of potential new male contraceptive strategies". The instant specification describes neither a agonist or an antagonist for a receptor of the instant as would be required to target that receptor in a contraceptive method. Further, the instant specification does not provide evidence or a credible line of reasoning which supports a conclusion that the administration of a protein of the instant invention to an individual would result in an immune response or that such an immune response would be contraceptive. A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. There is not a single reference of record which has demonstrated the clinical application of an immunogenic portion of a G protein-

coupled receptor to achieve a desired effective immunological response. In the decision of *Genentec, Inc, v. Novo Nordisk*, 42 USPQ 2d 100,(CAFC 1997), the court held that:

"[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure". The court further stated that "when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

The instant specification is not enabling because one can not follow the guidance presented therein and use the claimed protein as a male contraceptive or target thereof without first making a substantial inventive contribution.

Until some actual and specific significance can be attributed to the protein identified in the specification as "ESRP", and in Applicant's publication as "HE6", or the gene encoding it, the instant invention is incomplete. The protein encoded by a DNA of the instant invention is a compound known to be structurally analogous to proteins which are known in the art as G protein-coupled receptors. In the absence of a knowledge of the natural ligands or biological significance of this protein, there is no immediately obvious patentable use for it. To employ a protein of the instant invention in the identification of substances which inhibit or induce its activity is clearly to use it as the object of further research which has been determined by the courts to be a utility which, alone, does not support patentability. Since the instant specification does not

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disclose a credible "real world" use for "ESRP" then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

4) Claims 1 to 5, 17, 21 and 22 are rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.

5) Claims 1 to 3, 5 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5.1) Claims 1 to 3, 5 and 17 are vague and indefinite in reference to the term "derivative". Because the instant specification does not identify that property or combination of properties which is unique to and, therefore, definitive of a "derivative" of a protein having the amino acid sequence presented in SEQ ID NO:2 of the instant application an artisan can not determine if a compound which meets all of the other limitations of a claim, if any, would then be included or excluded from the claimed subject matter by the presence of this limitation.

5.2) Claims 2, 3 and 5 are vague and indefinite because they appear to be drawn to both a protein and a fragment, each of which appears to be an alternative embodiment of the other.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

35 U.S.C. § 120 states that:

An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

6) Claims 1 to 5, 17, 21 and 22 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by the Osterhoff et al. publication (DNA and Cell Biol. 16(4):379-389, Apr. 1997). Osterhoff et al. provided a written description of the claimed protein more than one year before the filing of the instant application. Applicant is advised that the instant application can only receive benefit under 35 U.S.C. § 120 from an earlier application which meets the requirements of 35 U.S.C. § 112, first paragraph, with respect to the now claimed invention. Because the instant application does not meet the requirements of 35 U.S.C. § 112, first paragraph, for those reasons given above and it is a divisional of application Serial Number 09/731,657, the prior application also fails to meet those requirements and, therefore, is unavailable under 35 U.S.C. § 120.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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